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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,579	10/27/2003	Jayesh Mehta	01017/39555	3753

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EXAMINER	
GALVEZ, JAMES JASON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,579	MEHTA ET AL.	
	Examiner	Art Unit	
	J. Jason Galvez	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

The amendment filed on 1/21/2005 has been entered. Claims 1-7 and 9-10 are pending in the instant application and are under examination in this office action. Claim 8 has been withdrawn. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

35 U.S.C. § 112, 1st paragraph

The rejection of claim 1 under 35 U.S.C. 1st paragraph regarding an "effective amount" has been withdrawn upon further consideration and in response to Applicant's arguments.

35 U.S.C. § 112, 2nd paragraph

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment of the claim.

Claim Rejections/Objections Maintained

35 U.S.C. § 102(b)

The rejection of claims 1, 2, and 9 under 35 U.S.C. 102(b) as anticipated by Orlic *et al.* is maintained for reasons of record in the office action of 10/20/2004. Applicant argues that Orlic *et al.* teach mobilization of bone marrow cells "prior to acute myocardial infarction (AMI)". Applicant also argues that Orlic *et al.* administered G-CSF

prophylactically and not after the ischemia event, which is asserted to be a point that sets the claimed invention apart from the prior art. In addition, Applicant argues that G-CSF is not disclosed as used alone or after arterial occlusion and that Orlic *et al.* "attributed most of the success of their method to SCF" (p. 5: paragraph 1). Finally, regarding dependent claim 2, Applicant argues that under 35 U.S.C. § 112, 4th paragraph, this dependent claim cannot stand rejected because it depends from claim 1, which is asserted to be free of the cited prior art because Orlic *et al.* do not meet all the limitations of the independent claim.

Applicant's arguments have been fully considered and have not been found persuasive. Orlic *et al.* teach the administration of a composition comprising G-CSF three days following coronary artery ligation, demonstrating that this composition was given following ischemia and not merely prophylactically (p. 10344: column 2, line 16; p. 10349: column 2, lines 5-7). Applicant's argument that G-CSF is not disclosed as used alone is moot because the claims read on a composition "comprising" G-CSF. The claims are drafted using open language and therefore precludes any argument relating to the use of G-CSF alone. Orlic *et al.* have not "attributed most of the success of their method to SCF", as argued by Applicant (p. 5: paragraph 1). Orlic *et al.* merely speculate, "SCF could be responsible..." for certain scenarios that may have contributed to the outcome of administering SCF and G-CSF compositions (p. 10349: column 1, paragraph 2). There are no experiments presented by Orlic *et al.* that can definitely show that SCF was primarily responsible for the outcome of the experiments, nor do Orlic *et al.* explicitly or implicitly support this erroneous interpretation. Since Orlic

et al. meet the limitations of the claim 1 and Applicant only argues the rejection of dependent claim 2 as a result of depending from a claim free of the prior art, the dependent claim stands rejected.

The rejection of claims 1-7 and 9-10 under 35 U.S.C. 102(b) as anticipated by Anversa *et al.* is maintained for reasons of record in the office action of 10/20/2004. Applicant argues that Anversa *et al.* do not teach a method of reperfusion therapy by administering G-CSF alone following ischemia (*i.e.* after AMI). Applicant states that Example 2 exemplifies that Anversa do not teach a method of reperfusion therapy using G-CSF in an effort to "improve patient outcome or increased ventricular wall thickness" (p. 6: paragraph 2). Applicant further argues that Anversa *et al.* do not disclose or contemplate a treatment using G-CSF following arterial occlusion. Finally, Applicant argues dependent claims 2-7, which depend from claim 1, and claim 10, which depends from claim 9, should not be rejected because they depend from claim 1 and 9, which are asserted to be free of the cited prior art because Anversa *et al.* do not meet all the limitations of the independent claims.

Applicant's arguments have been fully considered and have not been found persuasive. Currently the claims are drafted using open language and it should be noted that this language is inconsistent with Applicant's argument regarding using G-CSF alone. As a result of the manner in which the claims are drafted, *e.g.* a composition comprising G-CSF, Anversa *et al.* do meet the limitations of the claims (see previous office action). Furthermore, the composition comprising G-CSF was given for

three days following coronary artery occlusion (p. 14: paragraph [0177]). Since Anversa *et al.* meet the limitations of the claim 1 and Applicant only argues the rejection of dependent claim 2-7 as a result of depending from a claim free of the prior art, the dependent claims stand rejected. Applicant has erroneously stated that claim 10 depends from claim 9. However, claim 10 clearly falls under the scope of the cited prior art because the method disclosed by Anversa *et al.* are drawn to method of treating cardiovascular diseases, including ischemia, and define ischemic events as encompassing clinical scenarios such as bypass surgery (p. 1: paragraph [0003] and p. 2: [0014], respectively).

In an effort to further prosecution and address all of Applicant's arguments, the issue of using G-CSF alone will be addressed here even though the claims are broadly drafted and read on methods of using compositions comprising G-CSF. The methods disclosed by Anversa *et al.* are drawn to treating cardiovascular diseases, including ischemia, and taking advantage of the regenerative properties of stem cells that may restore cardiac function (p. 1: paragraph [0003] and p. 2: paragraph [0022], respectively). Furthermore, Anversa *et al.* state that administration of cytokines following ischemia restores "structural and functional integrity to the infarcted area" (p. 3: paragraph [0038]). The lack of specific examples, such as Example 2 as pointed out by Applicant, showing data regarding the use of G-CSF alone does not render Anversa *et al.* unable to anticipate the instant invention. Anversa *et al.* plainly state, "Another aspect of the invention relates to the administration of a cytokine" and that G-CSF is known in the art to stimulate "mobilization of stem cells" (p. 10: paragraph [0129]). Thus

Anversa clearly teaches the administration of G-CSF, and other cytokines that mobilize stem cells, in a treatment directed to ischemia and reperfusion. In addition, Anversa *et al.* intend this method to encompass administering the composition following ischemia by reciting, "...once the stem cells have mobilized into the blood stream, they home to the damaged area of the heart..." and "...involve the stem cells migrating into the infarcted area..." (p. 11: paragraphs [0134] – [0135]. For stem cells to "home to the damaged area of the heart" or migrate "into the infarcted area", the heart must have already been subjected to ischemia resulting in injured regions of the heart. Therefore, Anversa *et* al. teach administering compositions comprising G-CSF, as well as G-CSF alone, and administering said compositions following ischemia, which anticipates the instant claims.

35 U.S.C. § 112, 1st paragraph

The rejection of claims 1 and 5 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate in scope with the claims is maintained for reasons of record in the office action of 10/20/2004. Applicant argues that undue experimentation would not be required to practice the invention. Applicant states that the specification "provides a reasonable amount of guidance...to determine reduction in heart damage" (p. 7: paragraph 4). Applicant argues that a person of ordinary skill in the art "would look for reductions in heart damage" through various assays, *e.g.* decreased apoptosis (p. 8: paragraph 1). Applicant further argues that the specification can exclude what is well-known in the art and that if at least one method of making and using is presented that correlates in scope to the invention as claimed, the invention is enabled (*In re*

Buchner and *In re Fisher and MPEP § 2164.01(b)*). Regarding the use compositions comprising the various cytokines used, Applicant argues that all of the cytokines recited have been shown to stimulate growth and proliferation of hematopoietic cells. Applicant also specifically argues that IL-8 mobilizes progenitor cells and "may be helpful in assisting repair or prevention of heart damage after an AMI" and that the recited cytokines "may be useful in combination with G-CSF in reducing damage to the infarcted area of the heart" (p. 10: paragraph 1-2).

Applicant's arguments have been fully considered and are not found persuasive. Applicant is arguing that routine experimentation can be used to determine heart damage, which is not the issue with the recitation of the instant invention to "reduce heart damage". Applicant is directed to the previous office action. The issue at hand is whether or not the claimed method can reduce all forms of heart damage, as the instant claims broadly recite a method to "reduce heart damage". As stated in the previous office action reducing heart damage encompasses protection against a myriad of deleterious consequences following AMI. Although it is true, as stated by Applicant, that the specification can exclude what is well-known in the art and that if at least one method of making and using is presented that correlates in scope to the invention as claimed, the invention is enabled. However, the methods presented do not correlate in scope to the invention as claimed. Presently, the claims read too broadly based on what is disclosed. For example, does the claimed method protect against damage to specific components within the mitochondrial electron transport chain?

Regarding the use of compositions comprising additional cytokines with G-CSF, Applicant's arguments are speculative in nature. Applicant states at least twice that using additional cytokines "may" provide protective effects. Specifically, IL-8 has been claimed to be useful within the framework of the present invention. The literature supports the role of IL-8 as a proinflammatory cytokine (see previous office action). Until discrepancies have been worked pertaining to certain cytokines having proinflammatory properties and the ability to promote growth and proliferation of hematopoietic cells it would be considered an invention to experiment, not a patentable invention.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

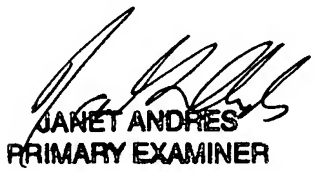
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J. Jason Galvez, Ph.D**. whose telephone number is **571-272-2935**. The examiner can normally be reached Monday through Friday 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached at **571-272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).



JJG
03/17/2005